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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,235	11/06/2001	Seth Lederman	2516-1-002N	5392

23565 7590 08/25/2003

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EXAMINER
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DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/25/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/992,235

**Applicant(s)**

LEDERMAN ET AL.

**Examiner**

Cybille Delacroix-Muirheid

**Art Unit**

1614

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8 is/are allowed.
- 6) ☒ Claim(s) 9-20 and 22 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Detailed Action***

The following is responsive to Applicant's amendment received March 5, 2003.

No claims are cancelled. No new claims are added. Claims 1-22 are currently pending.

The previous rejection of claims 1-8 under 35 USC 103(a) over Wolter et al. 5,462,746 or Midha et al., 6,217,904, maintained in the office action mailed Dec. 3, 2002, **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 9-22 under 35 USC 103(a) over Midha et al., supra in view of Wolter et al., supra, maintained in the office action mailed Dec. 3, 2002, **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claims rejection under 35 USC 112, paragraph 1, set forth at paragraph 4 of the office action mailed Dec. 3, 2002, **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, upon further consideration, the Examiner respectfully submits that claim 9 raises an additional issue, which is addressed below.

***New Ground of Rejection***

***Claim Rejections - 35 USC § 112***

1. Claims 9-20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are

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drawn to a method of treating a "human condition or disease requiring or benefiting from a central nervous system stimulant" comprising administering to a human in need thereof an effective amount of a composition comprising (R,R')(R,S')-amphetaminil sulfate substantially free of (S,R')(S,S')-amphetaminil. The claimed method of treatment fails to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1. There is insufficient descriptive support for the generic limitation "human condition or disease requiring or benefiting from a central nervous system stimulant." Furthermore, the claimed method requires treatment of an unspecified disease and no evidence indicates that a treatable disease, other than those listed at pages 3-4 of the specification, was known to Applicant. In the absence of some understanding of other diseases to be treated, one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed method.

2. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Allowable Subject Matter***

Claims 1-8 are free from the prior art because the prior art does not teach or fairly suggest Applicant's claimed pharmaceutical composition.

#### ***Conclusion***

Claims 1-8 are allowable.


Claim 9-20 and 22 are rejected.


Claim 21 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM   
August 20, 2003

  
Cybille Delacroix-Muirheid  
Patent Examiner Group 1600